

IN THE UNITED STATES DISTRICT COURT  
MIDDLE DISTRICT OF ALABAMA 2020  
NORTHERN DIVISION

CHIQUITA L. MCKINNES,

Plaintiff,

V.

JOHNSON & JOHNSON, INC., et al.,

Defendants.

**INC., JOHNSON & JOHNSON**

## PHARMACEUTICAL RESEARCH &

**DEVELOPMENT, LLC, BRAD MORROW**

## AND JAMIE FORBES' ANSWER TO

# PLAINTIFF'S COMPLAINT

**(JURY DEMAND ENDORSED HEREON)**

Defendants Johnson & Johnson (improperly plead as “Johnson & Johnson, Inc.”), Ortho-McNeil Pharmaceutical, Inc., Johnson & Johnson Pharmaceutical Research & Development, LLC, Brad Morrow and Jamie Forbes (“Defendants”), by and through counsel, hereby respond to the allegations set forth in Plaintiff’s Complaint as follows:

1. Defendants deny for want of knowledge, information, and otherwise each and every allegation and averment set forth in Paragraph 1.
2. Defendants admit that Johnson & Johnson is a New Jersey corporation with its principal place of business in New Jersey and further answering, deny each and every remaining allegation and averment set forth in Paragraph 2.
3. Defendants deny each and every allegation and averment set forth in Paragraph 3.
4. Defendants deny each and every allegation and averment set forth in Paragraph 4.

5. Defendants admit that defendant Johnson & Johnson Pharmaceutical Research & Development, LLC is a New Jersey Limited Liability Company with its principal place of business in New Jersey and further answering, deny each and every remaining allegation and averment set forth in Paragraph 5.

6. Defendants admit that defendant Ortho-McNeil Pharmaceutical, Inc. and/or defendant Johnson & Johnson Pharmaceutical Research & Development, LLC tested, designed, manufactured, labeled, promoted, marketed, sold and distributed the prescription drug Ortho Evra® and further answering, deny each and every remaining allegation and averment set forth in Paragraph 6.

7. Defendants admit that defendant Johnson & Johnson Pharmaceutical Research & Development, LLC performs research and development work for the pharmaceutical business units of Johnson & Johnson and therefore further answering, deny each and every remaining allegation and averment set forth in Paragraph 7.

8. Defendants admit that defendant Ortho-McNeil Pharmaceutical, Inc. is a subsidiary of defendant Johnson & Johnson and is a Delaware corporation with its principal place of business in New Jersey and further answering, deny each and every remaining allegation and averment set forth in Paragraph 8.

9. Defendants admit that defendant Ortho-McNeil Pharmaceutical, Inc. and/or defendant Johnson & Johnson Pharmaceutical Research & Development, LLC tested, designed, manufactured, labeled, promoted, marketed, sold and distributed the prescription drug Ortho Evra® and further answering, deny each and every remaining allegation and averment set forth in Paragraph 9.

10. Defendants admit that defendant Ortho-McNeil Pharmaceutical, Inc. does business in the state of Alabama and that defendant Ortho-McNeil Pharmaceutical, Inc. manufactured, advertised, promoted, marketed, sold and distributed the prescription drug Ortho Evra® and further answering, deny each and every remaining allegation and averment set forth in Paragraph 10.

11. Defendants admit that Brad Morrow is a resident of Alabama and is employed as a sales representative of defendant Ortho-McNeil Pharmaceutical, Inc. and further answering, deny each and every remaining allegation and averment set forth in Paragraph 11.

12. Defendants admit that Jamie Forbes is a resident of Alabama and is employed as a sales representative of defendant Ortho-McNeil Pharmaceutical, Inc. and further answering, deny each and every remaining allegation and averment set forth in Paragraph 12.

13. To the extent that this paragraph alleges wrongful conduct on the part of Defendants, such allegations are denied and further answering, Defendants are without knowledge or information sufficient to form a belief as to the remaining allegations set forth in Paragraph 13.

14. To the extent that this paragraph alleges wrongful conduct on the part of Defendants, such allegations are denied and further answering, Defendants are without knowledge or information sufficient to form a belief as to the remaining allegations set forth in Paragraph 14.

15. Defendants deny each and every allegation and averment set forth in Paragraph 15.

16. Defendants deny for want of knowledge, information, and otherwise each and every allegation and averment set forth in Paragraph 16.

17. Defendants admit that the prescription drug Ortho Evra® is a transdermal contraceptive patch and further answering, Defendants deny each and every remaining allegation and averment set forth in Paragraph 17.

18. Defendants admit that defendant Ortho-McNeil Pharmaceutical, Inc. and/or defendant Johnson & Johnson Pharmaceutical Research & Development, LLC tested, designed, created, manufactured, labeled, advertised, marketed, packaged, sold, supplied and distributed the prescription drug Ortho Evra® and further answering, deny each and every remaining allegation and averment set forth in Paragraph 18.

19. Defendants deny each and every allegation and averment set forth in Paragraph 19.

20. Defendants deny each and every allegation and averment set forth in Paragraph 20.

21. Defendants deny each and every allegation and averment set forth in Paragraph 21.

22. Defendants admit that defendant Johnson & Johnson Pharmaceutical Research & Development, LLC. filed a New Drug Application for Ortho Evra® with the FDA on or about December 21, 2000, denoted as NDA 21-180 and further answering, Defendants deny each and every remaining allegation and averment set forth in Paragraph 22.

23. Defendants deny each and every allegation and averment set forth in Paragraph 23.

24. Defendants admit that clinical trials were conducted, pursuant to an FDA approved NDA, which were reviewed by the FDA prior to FDA approval of Ortho Evra® for

prescription drug use by physicians and further answering, Defendants deny each and every remaining allegation and averment set forth in Paragraph 24.

25. Defendants deny each and every allegation and averment set forth in Paragraph 25.

26. Defendants state that the actions and publications of the FDA speak for themselves and further answering, Defendants deny each and every allegation and averment set forth in Paragraph 26.

27. Defendants admit that on or about November 20, 2001, the FDA approved the use of Ortho Evra® as a prescription drug for use by physicians for the prevention of pregnancy and further answering, Defendants deny each and every remaining allegation and averment set forth in Paragraph 27.

28. Defendants deny each and every allegation and averment set forth in Paragraph 28.

29. In response to the allegations and averments set forth in Paragraph 34, Defendants admit that such Paragraph describes certain language of the Ortho Evra® package insert and further answering, Defendants deny each and every remaining allegation and averment set forth in Paragraph 29.

30. Defendants admit that as with all prescription medicine, adverse events are reported to the FDA by a variety of people and entities and further answering, Defendants deny each and every remaining allegation and averment set forth in Paragraph 30.

31. Defendants admit that as with all prescription medicine, adverse events are reported to the FDA by a variety of people and entities and further answering, Defendants deny each and every remaining allegation and averment set forth in Paragraph 31.

32. Defendants deny each and every allegation and averment set forth in Paragraph 32.

33. Defendants deny each and every allegation and averment set forth in Paragraph 33.

34. Defendants deny each and every allegation and averment set forth in Paragraph 34.

35. Defendants deny each and every allegation and averment set forth in Paragraph 35.

36. Defendants deny each and every allegation and averment set forth in Paragraph 36.

**ANSWER TO COUNT I**

37. Defendants incorporate by reference, as if fully set forth herein, the answers to Paragraphs 1 through 36 of Plaintiff's Complaint.

38. Defendants deny each and every allegation and averment set forth in Paragraph 38.

39. Defendants deny each and every allegation and averment set forth in Paragraph 39.

40. Defendants admit that defendant Ortho-McNeil Pharmaceutical, Inc. and/or defendant Johnson & Johnson Pharmaceutical Research & Development, LLC tested, designed, analyzed, manufactured, labeled, advertised, marketed, sold, supplied and distributed the prescription drug Ortho Evra® and further answering, deny each and every remaining allegation and averment set forth in Paragraph 40.

41. Defendants admit that defendant Ortho-McNeil Pharmaceutical, Inc. and/or defendant Johnson & Johnson Pharmaceutical Research & Development, LLC tested, designed, analyzed, manufactured, labeled, advertised, marketed, sold, supplied and distributed the prescription drug Ortho Evra®. Defendants are without knowledge or information sufficient to form a belief regarding whether Ortho Evra® reached plaintiff without substantial change. Further answering, Defendants deny each and every remaining allegation and averment set forth in Paragraph 41.

42. Defendants deny each and every allegation and averment set forth in Paragraph 42 and controvert the prayer for relief set forth in the unnumbered paragraph following Paragraph 42.

#### **ANSWER TO COUNT II**

43. Defendants incorporate by reference, as if fully set forth herein, the answers to Paragraphs 1 through 42 of Plaintiff's Complaint.

44. Defendants state that they were subject only to those duties imposed by applicable law, and deny each and every allegation and averment set forth in Paragraph 44 to the extent they suggest any different or greater duties. Defendants further deny that they failed to abide by any applicable legal duties.

45. Defendants deny each and every allegation and averment set forth in Paragraph 45.

46. Defendants deny each and every allegation and averment set forth in Paragraph 46.

47. Defendants deny each and every allegation and averment set forth in Paragraph 47.

48. Defendants deny each and every allegation and averment set forth in Paragraph 48 and controvert the prayer for relief set forth in the unnumbered paragraph following Paragraph 48.

**ANSWER TO COUNT III**

49. Defendants incorporate by reference, as if fully set forth herein, the answers to Paragraphs 1 through 48 of Plaintiff's Complaint.

50. Defendants admit that defendant Ortho-McNeil Pharmaceutical, Inc. and/or defendant Johnson & Johnson Pharmaceutical Research & Development, LLC manufactured, packaged, promoted, advertised, sold, distributed and supplied the prescription drug Ortho Evra® and further answering, Defendants deny for want of knowledge, information, and otherwise each and every remaining allegation and averment set forth in Paragraph 50.

51. Defendants deny for want of knowledge, information, and otherwise each and every allegation and averment set forth in Paragraph 51.

52. Defendants deny each and every allegation and averment set forth in Paragraph 52 and controvert the prayer for relief set forth in the unnumbered paragraph following Paragraph 52.

**ANSWER TO COUNT IV**

53. Defendants incorporate by reference, as if fully set forth herein, the answers to Paragraphs 1 through 52 of Plaintiff's Complaint.

54. Defendants deny each and every allegation and averment set forth in Paragraph 54.

55. Defendants deny each and every allegation and averment set forth in Paragraph 55.



56. Defendants deny each and every allegation and averment set forth in Paragraph 56 and controvert the prayer for relief set forth in the unnumbered paragraph following Paragraph 56.

**ANSWER TO COUNT V**

57. Defendants incorporate by reference, as if fully set forth herein, the answers to Paragraphs 1 through 56 of Plaintiff's Complaint.

58. Defendants deny each and every allegation and averment set forth in Paragraph 58.

59. Defendants deny each and every allegation and averment set forth in Paragraph 59.

60. Defendants deny each and every allegation and averment set forth in Paragraph 60.

61. Defendants deny for want of knowledge, information, and otherwise each and every allegation and averment set forth in Paragraph 61.

62. Defendants deny each and every allegation and averment set forth in Paragraph 62 and controvert the prayer for relief set forth in the unnumbered paragraph following Paragraph 62.

**ANSWER TO COUNT VI**

63. Defendants incorporate by reference, as if fully set forth herein, the answers to Paragraphs 1 through 62 of Plaintiff's Complaint.

64. Defendants state that they were subject only to those duties imposed by applicable law, and deny each and every allegation and averment set forth in Paragraph 64 to the extent they suggest any different or greater duties. Defendants further deny that they failed to abide by any applicable legal duties.

65. Defendants deny each and every allegation and averment set forth in Paragraph 65.

66. Defendants deny for want of knowledge, information, and otherwise each and every allegation and averment set forth in Paragraph 66.

67. Defendants deny each and every allegation and averment set forth in Paragraph 67.

68. Defendants deny each and every allegation and averment set forth in Paragraph 68.

69. Defendants deny each and every allegation and averment set forth in Paragraph 69.

70. Defendants deny for want of knowledge, information, and otherwise each and every allegation and averment set forth in Paragraph 70.

71. Defendants deny each and every allegation and averment set forth in Paragraph 71 and controvert the prayer for relief set forth in the unnumbered paragraph following Paragraph 71.

#### **ANSWER TO COUNT VII**

72. Defendants incorporate by reference, as if fully set forth herein, the answers to Paragraphs 1 through 71 of Plaintiff's Complaint.

73. Defendants deny each and every allegation and averment set forth in Paragraph 73.

74. Defendants deny each and every allegation and averment set forth in Paragraph 74.

75. Defendants deny each and every allegation and averment set forth in Paragraph 75.

76. Defendants deny for want of knowledge, information, and otherwise each and every allegation and averment set forth in Paragraph 76.

77. Defendants deny each and every allegation and averment set forth in Paragraph 77 and controvert the prayer for relief set forth in the unnumbered paragraph following Paragraph 77.

#### **ANSWER TO DAMAGES**

78. Defendants deny each and every allegation and averment set forth in Paragraph 78 and controvert the prayer for relief set forth in Paragraph 78.

79. Defendants deny each and every allegation and averment set forth in Paragraph 79 and controvert the prayer for relief set forth in Paragraph 79.

80. Paragraph 80 does not contain any allegations or averments against Defendants and therefore, no responsive answer is required.

#### **FIRST AFFIRMATIVE DEFENSE**

Plaintiff's Complaint fails to state a claim against these answering Defendants upon which relief may be granted.

#### **SECOND AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred by the applicable statute of limitations, statute of repose and/or by the equitable doctrines of laches and estoppel.

#### **THIRD AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred by the doctrines of informed consent, release and waiver.

**FOURTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred because the alleged damages, if any are proven, were not proximately caused by any act or omission of any of the Defendants.

**FIFTH AFFIRMATIVE DEFENSE**

If Plaintiff suffered any of the injuries, losses and damages alleged, then said injuries, losses and damages were a direct and proximate result of a responsible, superseding, and/or intervening cause.

**SIXTH AFFIRMATIVE DEFENSE**

Defendants state that if Plaintiff has suffered any of the injuries, losses and damages alleged, then said injuries, losses and damages were due to an allergic, idiosyncratic or idiopathic reaction to the product at issue in this case, or by an unforeseeable illness, unavoidable accident or preexisting condition, without any negligence and culpable conduct by Defendants.

**SEVENTH AFFIRMATIVE DEFENSE**

Plaintiff's injuries and damages, if any, were caused in whole or in part by the acts (wrongful or otherwise), negligence, sole fault, misuse, abuse, modification, alteration, omission or fault of one or more persons or entities over whom Defendants exercised no control and for whom Defendants are not legally responsible, including, without limitation, Plaintiff.

**EIGHTH AFFIRMATIVE DEFENSE**

Plaintiff failed to exercise reasonable care and diligence to mitigate injuries and damages, if any.

**NINTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred by the "state of the art" and "state of scientific knowledge" defenses.

**TENTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred by the Learned Intermediary Doctrine.

**ELEVENTH AFFIRMATIVE DEFENSE**

The product at issue in this case falls under the auspices of the Food, Drug and Cosmetic Act and regulations promulgated by the Federal Food & Drug Administration, and therefore, Federal law preempts Plaintiff's claim. *See*, 21 U.S.C. §301 *et. seq.* *See also*, 71 Fed. Reg. 3922 (January 24, 2006).

**TWELFTH AFFIRMATIVE DEFENSE**

Defendants did not make to Plaintiff nor did they breach any express or implied warranties and/or breach any warranties created by law. To the extent that Plaintiff relies on any theory of breach of warranty, such claims are barred by applicable law, and for lack of privity with Defendants and/or for failure of Plaintiff, or Plaintiff's representatives, to give timely notice to Defendants of any alleged breach of warranty. Defendants further specifically plead as to any breach of warranty claim all affirmative defenses under the Uniform Commercial Code existing and which may arise in the future, as enacted in the State of Alabama, and any other state whose law is deemed to apply in this case.

**THIRTEENTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred by comments j and k to Section 402A of the Restatement (Second) of Torts.

**FOURTEENTH AFFIRMATIVE DEFENSE**

Plaintiff's claims of product defects are barred by Section 2, 4, and 6(c) and (d) of the Restatement (Third) of Torts: Products Liability.

**FIFTEENTH AFFIRMATIVE DEFENSE**

Plaintiff's product liability claims are barred because the benefits of the relevant product outweighed its risks.

**SIXTEENTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred in whole or part because the product at issue was at all times properly prepared, packaged, and distributed, and was not defective or unreasonably dangerous.

**SEVENTEENTH AFFIRMATIVE DEFENSE**

Any imposition of punitive damages in this case against Defendants is barred to the extent that the manner in which such punitive damages are calculated violates the Constitution of the United States or the Constitution of the State of Alabama.

**EIGHTEENTH AFFIRMATIVE DEFENSE**

Any award of punitive damages in this case against Defendants is barred to the extent that the amount of such an award violates the Constitution of the United States or the Constitution of the State of Alabama.

**NINETEENTH AFFIRMATIVE DEFENSE**

Plaintiff has failed to plead fraud with specificity.

**TWENTIETH AFFIRMATIVE DEFENSE**

Defendants are entitled to a setoff for all amounts paid, payable by or available from collateral sources.

**TWENTY-FIRST AFFIRMATIVE DEFENSE**

Defendants plead the Alabama Sealed Package/Container (or Lack of Causal Relation) Doctrine.

**TWENTY-SECOND AFFIRMATIVE DEFENSE**

If any of the alleged injuries or damages were in fact sustained, they were the result of misuse of the subject product.

**TWENTY-THIRD AFFIRMATIVE DEFENSE**

Adequate and complete warnings and instructions were provided with the subject product, and the subject product was neither defective nor unreasonably dangerous when used according to label instructions.

**TWENTY-FOURTH AFFIRMATIVE DEFENSE**

If any of the alleged injuries were in fact sustained, they were caused in whole or in part by the injured person's own contributory negligence. The claimed damages are, therefore, barred.

**TWENTY-FIFTH AFFIRMATIVE DEFENSE**

Any express or implied warranties alleged to have been made by Defendants were disclaimed.

**TWENTY-SIXTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred or reduced by the doctrine of assumption of risk.

**TWENTY-SEVENTH AFFIRMATIVE DEFENSE**

Any recovery by Plaintiff must be reduced or offset by amounts Plaintiff received or will receive from others for the same injuries claimed in this lawsuit.

**TWENTY-EIGHTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred because Defendants did not owe any legal duty to Plaintiff, or, if Defendants did owe such a legal duty, Defendants did not breach that duty.

**TWENTY-NINTH AFFIRMATIVE DEFENSE**

The product at issue was not defective within the meaning of the Alabama Extended Manufacturer's Liability Doctrine.

**THIRTIETH AFFIRMATIVE DEFENSE**

With respect to Plaintiff's demand for punitive damages, Defendants specifically incorporate by reference all standards of limitations regarding the determination and enforceability of punitive damage awards which arose in the decisions of *BMW of North America v. Gore*, 517 U.S. 559 (1996), *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001), and *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408 (2003), together with all such standards applicable under Alabama law.

**THIRTY-FIRST AFFIRMATIVE DEFENSE**

Consideration of any punitive damages in this civil action would violate the due process clauses of the Fifth and Fourteenth Amendments to the United States Constitution by allowing standardless discretion to the jury to determine punishment and by depriving Defendants of prior notice of the consequences of its alleged acts.

**THIRTY-SECOND AFFIRMATIVE DEFENSE**

Punitive damages would be improper in this case under § 6-11-20(a) and (b), Code of Alabama (1975).



**THIRTY-THIRD AFFIRMATIVE DEFENSE**

Plaintiff's claims for punitive damages are barred or limited by § 6-11-21, et seq., Code of Alabama.

**THIRTY-FOURTH AFFIRMATIVE DEFENSE**

The post-verdict review of punitive damages adopted by the State of Alabama violates Article I, Section 11 of the Alabama Constitution because it permits the Court to review evidence not presented to the jury and apply legal standards on which the jury was not instructed.

**THIRTY-FIFTH AFFIRMATIVE DEFENSE**

Punitive damages are a punishment, a quasi-criminal sanction for which Defendants have not been afforded the specific procedural safeguards prescribed in the Alabama Constitution and the Fifth and Sixth Amendments to the United States Constitution.

**THIRTY-SIXTH AFFIRMATIVE DEFENSE**

Any imposition of punitive damages in this case against Defendants is barred to the extent that the manner in which such punitive damages are calculated violates the Constitution of the United States or the Constitution of the State of Alabama.

**THIRTY-SEVENTH AFFIRMATIVE DEFENSE**

Any award of punitive damages in this case against Defendants is barred to the extent that the amount of such an award violates the Constitution of the United States or the Constitution of the State of Alabama.

**THIRTY-EIGHTH AFFIRMATIVE DEFENSE**

Defendants hereby give notice that they intend to rely upon such other defenses as may become available or appear during discovery in this case or otherwise and hereby reserve the right to amend this Answer to assert any such defenses.

**THIRTY-NINTH AFFIRMATIVE DEFENSE**

Defendants specifically reserve the right to amend their Answer by adding defenses, counterclaims, cross claims or by instituting third party actions as additional facts are obtained.

WHEREFORE, having fully answered, Defendants Johnson & Johnson, Ortho-McNeil Pharmaceutical, Inc., Johnson & Johnson Pharmaceutical Research & Development, LLC, Brad Morrow and Jamie Forbes specifically controvert Plaintiff's Prayer for Relief as set forth in Plaintiff's Complaint.

Respectfully submitted,



JOSEPH P. H. BABINGTON (BABIJ7938)

THOMAS RYAN LUNA (LUNAT2309)

Attorneys for Defendants Johnson & Johnson,  
Ortho-McNeil Pharmaceutical, Inc., and Johnson &  
Johnson Pharmaceutical Research & Development,  
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**JURY DEMAND**

Defendants Johnson & Johnson, Ortho-McNeil Pharmaceutical, Inc., Johnson & Johnson Pharmaceutical Research & Development, LLC, Brad Morrow and Jamie Forbes hereby demand a trial by jury of all the facts and issues in this case pursuant to 38(b) of the Federal Rules of Civil Procedure.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "JPH Babington", written over a horizontal line.

JOSEPH P. H. BABINGTON (BABI7938)

THOMAS RYAN LUNA (LUNAT2309)

Attorneys for Defendants Johnson & Johnson,  
Ortho-McNeil Pharmaceutical, Inc., and Johnson &  
Johnson Pharmaceutical Research & Development,  
LLC

**CERTIFICATE OF SERVICE**

This is to certify that the above and foregoing **Answer of Defendants Johnson & Johnson, Ortho-McNeil Pharmaceutical, Inc., and Johnson & Johnson Pharmaceutical Research & Development, LLC**, has been served on the following counsel of record by placing a copy of the same in the United States Mail, postage prepaid and properly addressed, this 20 day of June, 2006:

Jere L. Beasley  
Andy D. Birchfield, Jr.  
Wesley Chadwick Cook  
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OF COUNSEL

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